

REMARKS

Summary of Office Action

In the Office Action, the Examiner rejected Applicant's claim for the benefit of a prior-filed application. In regard to the substantive examination of the claims, the Examiner rejected Claims 1 and 5 under 35 U.S.C. § 102(b) as being clearly anticipated by U.S. Patent Number 5,405,784 issued to Van Hoegaerden (hereinafter "Van Hoegaerden"). The Examiner also rejected Claim 1 under 35 U.S.C. § 102(e) as being clearly anticipated by U.S. Patent Number 6,974,704 issued to Nelson et al. (hereinafter "Nelson"). Finally, the Examiner rejected Claims 2-4 and 6-8 under 35 U.S.C. § 103(a) as being unpatentable over Van Hoegaerden or Nelson, each in view of U.S. Patent Number 5,981,298 issued to Chudzik et al. (hereinafter "Chudzik") and The Triage Panel for Drugs of Abuse, Biosite Diagnostics, 1991 (hereinafter "Panel").

Summary of Amendment

Upon entry of the present Amendment, Claim 5 will have been amended. As such, Claims 1-8 remain currently pending. By the present Amendment and Remarks, Applicant submits that the rejections have been overcome and respectfully requests reconsideration of the outstanding Office Action.

Applicant's Response

1. Priority Rejection

The Examiner's rejection of Applicant's claim for the benefit of a prior-filed application (specifically, Application Numbers 09/813,071; 09/295,847; and 09/195,309) and the resulting filing date of the present invention of October 28, 2003 are noted by Applicant.

2. Section 102(b) Rejection of Claims 1 and 5

The examiner submits that Van Hoegaerden discloses fluorescent latex beads having more than one antiligand fixed to their surface and that such antiligands are specific to more than one substance. *Office Action, Page 3*. The Examiner then admits that Van Hoegaerden

does not disclose that the antiligands are ligand analog protein complexes. *Id.* The Examiner, however, asserts that they are the same since the antiligand of Van Hoegaerden is defined as a molecular structure capable of recognizing and *binding specifically to the organic, biological, or medicinal substances to be detected.* *Office Action, Page 4.*

Applicant's independent Claim 1 recites, *inter alia*, "A dye for use in detecting the presence of two ... ligands ... via a competitive immunoassay utilizing receptors specific for ... ligands comprising: a particulate dye component; first and second *ligand analog protein complexes* absorbed upon said particulate dye; and wherein said ... ligand analog protein complexes ... are operative to bind with receptors for both said ... ligands."

The method of Van Hoegaerden requires, "...the formation of complexes by contact of the specimen with fluorescent beads on which is fixed at least one suitable *antiligand*..." *Column 5, lines 19-22* (emphasis added). Furthermore, as the Examiner admitted, Van Hoegaerden defines an antiligand as, "...a molecular structure capable of *recognizing and binding specifically to the* one or more organic, biological or medicinal *substances to be sought*..." *Column 3, lines 23-26* (emphasis added).

As such, the Van Hoegaerden reference functions by having the fluorescent beads bind directly to the substance to be detected in order to measure the amount of the substance in a sample. This is in sharp contrast to the method of Applicant's claimed invention wherein the particulate dye includes ligand *analog* protein complexes and further includes ligand receptors capable of binding either to the ligand of interest *or to the ligand analog protein complexes present on the particulate dye.* The Examiner admits that Van Hoegaerden does not state that the antiligands are ligand analog proteins; Van Hoegaerden does not state this because that would be against what Van Hoegaerden teaches, specifically, the binding of the fluorescent beads directly to the ligand of interest for purposes of agglutinization. As such, Applicant's claimed invention and the method of the Van Hoegaerden reference are directed to two very different functions.

For the foregoing reasons and because Van Hoegaerden fails to disclose the above-noted features of the present invention, Applicant submits that Van Hoegaerden fails to disclose each and every recited feature of the present invention as recited in independent Claim 1.

Accordingly, an adequate evidentiary basis to support the rejection under 35 U.S.C. § 102(b) has not been established and the present rejection of Claim 1 is improper and should be withdrawn.

Applicant further submits that the Claim 5 is allowable at least for the reason that it depends on allowable independent Claim 1 and because it recites additional features that further define the present invention.

3. Section 102(e) Rejection of Claim 1

The Examiner merely submits that Nelson discloses affinity reagents comprising one or several different antigens immobilized to a solid substrate which can be agarose beads, nylon, metals, glass, silicon, and organic membranes. *Office Action, Page 4.*

Applicant's independent Claim 1 recites, *inter alia*, "A dye for use in detecting the presence of two ... ligands ... via a competitive immunoassay utilizing receptors specific for ... ligands comprising: a particulate dye component; first and second ligand analog protein complexes absorbed upon said particulate dye; and wherein said ... ligand analog protein complexes ... are operative to bind with receptors for both said ... ligands."

In contrast, Nelson discloses a method which utilizes, "...an antibody or antigen to capture and isolate another antigen or antibody, respectively, from its surroundings and thereafter mass spectrometrically analyze the isolated antibody or antigen after release from the capturing agent." *Column 3, lines 1-4* (emphasis added). In order to do this, Nelson discloses that, "Antibodies to each antigen to be detected are immobilized on a solid substrate creating the affinity reagent...[which] is then incubated with the specimen to screen the specimen for any antigen present in the specimen that has an affinity for the affinant-antibody immobilized on the affinity reagent...for enough time to allow the affinant-antibody to combine with a detectable amount of antigen for which it has a specific affinity." *Column 9, lines 55-64.*

Nelson discloses an antiligand immobilized onto a solid substrate wherein the antiligand is capable of combining with the ligand of interest in a specific sample. The ligand captured by the immobilized antiligand can then be measured by mass spectrometry. This is in contrast, to Applicant's invention which is directed toward a simple to use test for

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detecting the presence of ligands in a sample and does not require sophisticated equipment such as mass spectrophotometers. Additionally, Applicant's claimed invention requires a particulate dye having ligand analog protein complexes absorbed thereupon. These ligand analogs are able to compete with the ligands of interest in binding with receptors. Nelson in no way teaches or suggests the use of ligand analogs to compete for binding with the antiligand, and there has been no showing whatsoever that Nelson teaches or suggests this recited element of Applicant's invention.

For the foregoing reasons and because Nelson fails to disclose the above-noted features of the present invention, Nelson fails to disclose each and every recited feature of the present invention as recited in independent Claim 1. Accordingly, an adequate evidentiary basis to support the rejection under 35 U.S.C. § 102(e) has not been provided and the present rejection of Claim 1 is improper and should be withdrawn.

4. Section 103(a) Rejection of Claims 2-4 and 6-8

The Examiner admits that Van Hoegaerden and Nelson do not teach conjugating morphine-3-beta-D-glucuronide or amphetamines to the dye particles. *Office Action, Page 5.* The Examiner, however, asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Van Hoegaerden or Nelson to include them since Chudzik and Panel teach that such conjugates are well known in the art and would be a mere alternative and functionally equivalent conjugation technique. *Office Action, Pages 5-6.* The Examiner also admits that none of the references teach the particulate dye being conjugated to 3, 4, or 5, different ligand analogs. *Office Action, Page 6.* To remedy this lack of teaching, the Examiner asserts that the references of record recognize the need to detect more than one analyte in the same sample and therefore it would be obvious to make the changes to reach Applicant's invention. *Id.*

The arguments presented above in regard to Van Hoegaerden and Nelson are incorporated herein by reference. As Applicant's independent Claim 1 has been shown to not be anticipated by either Van Hoegaerden or Nelson, Applicant respectfully submits that dependent Claims 2-4 and 6-8 are allowable at least for the reason that these claims depend

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on allowable independent Claim 1 and because these claims recite additional features that further define the present invention

Conclusion

Applicant respectfully submits that each and every pending claim of the present invention meets the requirements for patentability under 35 U.S.C. §§ 102 and 103, and respectfully requests that the Examiner indicate allowance of each and every pending claim of the present invention.

In view of the foregoing, it is submitted that none of the references of record, either taken alone or in any proper combination thereof, anticipate or render obvious Applicant's invention as recited in each of Claims 1-8. The applied references of record have been discussed and distinguished, while significant claim features of the present invention have been pointed out.

Accordingly, reconsideration of the outstanding Office Action and allowance of the present application and all the claims therein are respectfully requested and now believed to be appropriate.

If any additional fee is required, please charge Deposit Account Number 19-4330.

Respectfully submitted,

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